K013092

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OCT 1 0 2001

BIOMET

CORPORATE HEADQUARTERS

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor:	Biomet Orthopedics, Inc. 56 East Bell Drive P.O. Box 587 Warsaw, IN 46581-0587
Contact Person:	Sara B. Shultz Biomet Manufacturing, Corp. P.O. Box 587 Warsaw, IN 46581-0587 Phone: (219) 267-6639 Fax: (219) 372-1683
Proprietary Name:	Discovery Elbow
Common Name:	Elbow Prosthesis
Product Classification:	Class II
Classification Name:	Elbow joint metal/polymer constrained cemented prosthesis (888.3150)
Device Product Code:	87JDC

Legally Marketed Devices To Which Substantial Equivalence is Claimed:
Constrained Elbow, K003253

Intended Use: The Constrained Elbow is indicated for use in the following conditions:

- Non-Inflammatory Degenerative Joint Disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Revisions where other treatments or devices have failed
- Correction of severe functional deformity
- Treatment of acute or chronic fractures with humeral epicondyle involvement which are unmanageable using other treatment methods

This device is intended for cemented use.

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Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
219.267.6639

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219.267.8137

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biomet@biomet.com

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Device Description: The Constrained Elbow is a total elbow prosthesis comprised of an ulnar and humeral component. The humeral components are available with or without an anterior flange. All ulnar and humeral components are manufactured with or without Bond coat.

The device design allows the load to be carried at the primary articulation. The primary articulation is the spherical interface between the humeral condyles and the ulnar bearing. The secondary articulation is the axle attached to one condyle, which fits into the hole of the opposite condyle. The geometry of the components is designed to minimize bone loss and eliminate sharp resection cuts.

The humeral stem has been designed to incorporate a five degree carrying angle with a five degree internal rotation to closely match the anatomical morphology. The ulnar component incorporates a bowed stem and neck angle also designed to closely match the anatomical morphology.

Summary of Technologies: The device's technological characteristics (materials, design, sizing, and indications) are similar to or identical to the predicate device.

Non-Clinical Testing: Finite Element Analysis was performed to establish substantial equivalence.

Clinical Testing: Clinical testing was not used to establish substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2001

Ms. Sara B. Shultz
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K013042
Trade/Device Name: Biomet Discovery Elbow
Regulation Number: 21 CFR 888.3150
Regulation Name: Elbow joint metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: JDC
Dated: September 5, 2001
Received: September 10, 2001

Dear Ms. Shultz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Divison of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known) : K013042

Device Name: Discovery Elbow

Indications For Use:

The Discovery Elbow is indicated for use with the following conditions:

- Non-Inflammatory Degenerative Joint Disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Revisions where other treatments or devices have failed
- Correction of severe functional deformity
- Treatment of acute or chronic fractures with humeral epicondyle involvement which are unmanageable using other treatment methods

This device is intended to be used with bone cement.

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative and Neurological Devices
510(k) Number K013042

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)